IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: Ethicon Wave 1 cases listed in Exhibit A	

PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR *DAUBERT* MOTION TO EXCLUDE FDA EXPERT TIMOTHY ULATOWSKI

This Court should exclude FDA expert Timothy Ulatowski from testifying in the Ethicon Wave 1 cases because he has no opinions that he is qualified to give that are also relevant to the litigation and admissible under Federal Rule of Evidence 403. Mr. Ulatowski's opinions are based on the FDA's regulatory scheme. Assuming the Court issues similar rulings as in prior cases, excluding FDA evidence, such opinions are irrelevant and should also be excluded under Rule 403. This Court has previously held that any discussion of the regulatory process creates a mini-trial on that issue, which will confuse the jury, waste time, and create unfair prejudice. If the Court rules similarly for Ethicon Wave 1, then Mr. Ulatowski's opinions should be excluded for that reason. Some of his opinions directly implicate the 510(k) clearance process, which the Court has directly excluded from MDL trials. Other opinions touch on different aspects of the regulations, but all FDA opinions present similar problems, in that they require extensive testimony on the regulations, taking the focus away from the true legal issues in the case. Such

discussion also suggests that the product was FDA approved, necessitating further testimony on the 510(k) process.

The Court should also exclude any opinions as to manufacturing, warnings in the Instructions for Use, and patient brochures, based on Mr. Ulatowski's lack of qualifications. Mr. Ulatowski does not have the expertise to opine about any of those issues—which he has admitted as to the content of warnings and brochures. Thus, either his opinions touch only on regulatory issues and should be excluded as irrelevant or under Rule 403; or, if his opinions stray outside of the regulatory context to evaluating the content of Ethicon's warnings, manufacturing processes, or brochures, those opinions fall outside of his expertise.

As a result, Mr. Ulatowski has no opinions that are both within his expertise and outside the rubric of the FDA evidence that this Court has consistently excluded. This Court, therefore, should exclude him completely from testifying in the Ethicon Wave 1 cases.

LEGAL STANDARDS

Federal Rule of Evidence 702 sets forth the basic framework for analyzing the admissibility of expert opinions. The rule reads, in pertinent part, as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702.

If the witness is suitably qualified, then the *Daubert* inquiry generally breaks down into a two-step analysis. The first issue is whether the proffered evidence represents "scientific knowledge," meaning that it is supported by appropriate validation. The second issue is whether the evidence would assist the jury—i.e., whether it is relevant. *United States v. Dorsey*, 45 F.3d

809, 813 (4th Cir. 1995). The relevance aspect of the inquiry is often discussed in terms of whether the expert's opinions "fit" the case. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591-92 (1993).

Under Rule 403, "[t]court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403.

ARGUMENT

I. This Court has consistently forbidden any presentation of evidence about the FDA's regulations and processes, as such evidence has little if any probative value while causing a great risk of confusion, prejudice, and wasted time.

This Court has been extremely consistent in its views about the presentation of FDA evidence at trial, and in fact the Court has addressed that issue regarding Mr. Ulatowski specifically.

This Court has already excluded Mr. Ulatowski's testimony because it touched on irrelevant and unduly prejudicial FDA issues, even though the motion filed against him was untimely. In the *Bellew* bellwether case, this Court wrote that "this court will not tolerate the presentation of evidence that touches on or in any way alludes to the 510(k) clearance process." *Bellew v. Ethicon, Inc.*, No. 2:13-CV-22473, 2014 WL 6680356, at *10 (S.D.W. Va. Nov. 25, 2014). The Court continued: "Furthermore, insofar as Mr. Ulatowski's opinions relate to FDA regulations or procedures, FDA decision-making, FDA communications, or Ethicon's compliance with such, they are **EXCLUDED.** I have previously expressed concern with the risks of leading the jury into the confusing domain of the FDA." *Id.* Thus, this Court excluded

all opinions that touched on FDA or other regulatory matters. The Court denied the motion as untimely as to any other potential issues. *Id.* at *11.

That ruling as to Mr. Ulatowski was consistent with the position that this Court has taken throughout this MDL, as to every device manufacturer. For instance in *Huskey*, another Ethicon case, this Court wrote that "I have repeatedly and thoroughly considered the admissibility of the FDA's 510(k) process, and I have consistently found that the 510(k) process does not relate to safety or efficacy." *Huskey v. Ethicon, Inc.*, No. 2:12-CV-05201, 2014 WL 1347372, at *1 (S.D.W. Va. Apr. 3, 2014). In *Cisson*, a Bard case, the Court's rulings excluding any FDA evidence were challenged on appeal, and the Fourth Circuit affirmed this Court's decisions. The Fourth Circuit noted that "devices approved under the 510(k) process may be marketed without premarket approval," and therefore the process "does operate to exempt devices from rigorous safety review procedures." *In re C.R. Bard, Inc., MDL. No. 2187, Pelvic Repair Sys. Prods. Liab. Litig.*, 810 F.3d 913, 920 (4th Cir. 2016). The Court of Appeals further concluded that the "clear weight of persuasive and controlling authority" supported this Court's decision to exclude evidence related to the FDA clearance process. *Id.* at 920-21.

Although much of the discussion has focused on the FDA's 510(k) process, this Court has further stated that any matters regarding the FDA's processes should be kept out of trials. Citing the Court's Order in *Sanchez v. Boston Scientific Corp.*, No. 2:12–cv–05762, 2014 WL 4851989, at *35–36 (S.D. W.Va. Sept. 29, 2014), this Court in *Bellew* expressed its concern that "expert testimony about the requirements of the FDCA, which are not at issue in this case, could lead to more confusion ... than enlightenment." *Bellew*, 2014 WL 6680356, at *10. Noting that Mr. Ulatowski's opinions touched solely on FDA-related matters, this Court excluded "any opinion testimony on matters of the FDA … ." *Id.*

In the *Cisson* appeal, the Fourth Circuit also discussed the issue of confusion and delay:

> In one of several related rulings, the court stated that bringing in such evidence would result in a "mini-trial" about (1) the strengths and weaknesses of the process and (2) whether Bard had in fact made all of the disclosures it should have made during the process. Bard's evidence would have initiated a battle of experts: Bard was prepared to characterize the review process as "thorough" and "robust" and the FDA's clearance of the Avaulta Plus as "an affirmative safety ... decision" based on "specific safety and efficacy findings." JA 613–15. Cisson was prepared to argue, as she has done before this Court, that these characterizations wildly inflate the significance of the process, and that in any event Bard failed to make necessary disclosures to the FDA.

In re C.R. Bard, 810 F.3d at 921-22. In addition to the obvious concern about wasting time, the court expressed the more serious concern that "having a 'mini-trial' could easily inflate the perceived importance of compliance and distract the jury from the central question before it—whether Bard's design was unreasonable based on any dangers it posed versus the costs required to avoid them." *Id.* at 922.

Plaintiffs are not, through this motion, moving for exclusion of all FDA evidence from the Wave 1 cases. Plaintiffs will address that issue later, during motions *in limine*. However, Plaintiffs are mindful of the Court's prior rulings, and this motion operates under the assumption that this Court will enter a similar ruling for the Ethicon Wave 1 cases.

II. Most of Mr. Ulatowski's opinions relate directly to FDA issues. All such opinions should be excluded as irrelevant, and also under Rule 403 because they have limited probative value while causing a substantial risk of prejudice, confusion, and delay.

Mr. Ulatowski, who spent 16 years with the FDA,[1] has been designated to testify on a variety of matters in more than 100 cases in Ethicon Wave 1. Some of these FDA opinions do not address the 510(k) clearance process directly, but almost all of them relate to regulatory issues. Such opinions have little if any probative value and present the same dangers of confusion, undue prejudice, and waste of time that are presented by opinions directly addressing

[1] Ulatowski CV, attached as Exhibit B, at pp. 1-2.

the 510(k) process. Once the FDA is injected into the trial in any shape, form or fashion, Plaintiffs will have no choice but to respond by explaining the whole process—to avoid any misconception that the FDA approved whatever device is at issue.

For the wave cases, Mr. Ulatowski has been designated to opine regarding the TVT, TVT-O, TVT-Exact, Gynemesh PS, and Prolift. His five expert reports on those topics total more than 400 pages and include a total of 70 opinions—TVT (16), TVT-O (15), TVT Exact (16), Gynemesh PS (10), and Profit (13).[2] It is not realistic to go through all 70 opinions and explain why most implicate regulatory issues, so this brief will go through all of Mr. Ulatowski's TVT-O opinions, and the same reasoning will apply to the other products.

1. **Assertion: The ProteGen recall does not affect the TVT-O**:[3] This opinion is clearly a regulatory opinion that would require in-depth analysis of the FDA processes and the reasons that the FDA might recall a product; it would also suggest that the TVT-O is approved by the FDA, because there would be no discussion of any TVT-O recall.

2. **Assertion: Prolene is supported by the FDA as safe and effective**:[4] This opinion is a back-door attempt to show FDA approval. Mr. Ulatowski's report states that "FDA and the medical community consider PROLENE containing devices, and therefore PROLENE to be clinically acceptable."[5] Such testimony would force Plaintiffs to explain that approval of Prolene generally does not indicate approval of any device containing Prolene—which leads directly to the question of whether the device actually at issue, the TVT-O, was approved. This Court has also recognized that "analyzing the component parts of a device separately from the

[2] Ulatowski TVT Report, attached as Exhibit C; Ulatowski TVT-O Report, attached as Exhibit D; Ulatowski TVT Exact Report, attached as Exhibit E; Ulatowski Gynemesh PS Report, attached as Exhibit F; Ulatowski Prolift Report, attached as Exhibit G.
[3] Ulatowski TVT-O Report, Ex. D, at 57.
[4] *Id.* at 59.
[5] *Id.*

device itself simply does not make sense." *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 760 (S.D. W. Va. 2014).

3. **Assertion: Changing the TVT-O would require a new 510(k) clearance**:[6] The 510(k) clearance process is directly implicated; therefore, this opinion is clearly irrelevant and unduly prejudicial under the Court's prior orders.

4. **Assertion: There is no reason for the FDA to recommend labeling changes for the TVT-O**:[7] Again, the FDA is directly implicated, this time in terms of labeling. If Mr. Ulatowski is allowed to opine that the FDA had no reason to change the labeling, there are at least two major problems. First, the parties would have to explain the labeling process to the jury and fight about when it is appropriate for the FDA to propose a change. Second, this opinion strongly suggests that the FDA has approved the device, by discussing FDA action on labeling. If this opinion were given, Plaintiffs would be forced to explain the whole 510(k) process, to try to avoid any confusion as to whether the device had been approved by the FDA. Finally, as discussed in Section III, Dr. Ulatowski is not a warnings expert.

5. **Assertion: FDA pronouncements on patient brochures**:[8] This opinion is a classic example of an opinion offering "more confusion than enlightenment." Ultimately, Mr. Ulatowski concludes that it was reasonable and proper for Ethicon to provide patient brochures. But that does not get to the heart of the issue about the brochures. The issue is about the content of the patient brochures, which the opinion does not address. If the opinion is solely about what the FDA requires in brochures, then again there is a major issue of confusion and wasted time, and the same problem of implicitly suggesting that the device is approved.

[6] Ulatowski TVT-O Report at 62.
[7] *Id.* at 64.
[8] *Id.* at 65.

6. **Assertion: There are no regulatory requirements for patient brochures, and the TVT-O brochures are appropriate**:[9] This clearly is two opinions in one. Any suggestion that patient brochures cannot be characterized as labeling is flat wrong.[10] Regardless, the question of what the FDA considers labeling presents the same problems as those describes as to Opinion (5). The opinion that the brochures are appropriate should be excluded for the reasons discussed in Section III below. By his own admission, Dr. Ulatowski is not an expert in that area.

7. **Assertion: The TVT-O was adequately manufactured**.[11] This opinion is based solely on FDA documents, not on any observance of Ethicon's manufacturing practices.[12] Thus, if the opinion is given, there would need to be evidence presented on what Warning Letters are, what Issue Reports are, what MDRs are, and whether a small number of such documents actually means something. In addition, Mr. Ulatowski is not qualified to give the opinion, as discussed in Section III below.

8. **Assertion: Ethicon's device reporting procedures complied with FDA regulations**:[13] This opinion is directed straight to FDA issues and should clearly be excluded other the Court's prior rulings. Allowing it would necessitate a trial within a trial about what the FDA requires and what Ethicon actually did to report adverse events.

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[9] *Id.* at 67.
[10] *See FDA: Introduction to Device Labelling*, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/DeviceLabeling/ucm2005422.htm (last visited April 19, 2016) (stating that information "accompanying" a device is labeling and including brochures and pamphlets in the description of such information).
[11] *Id.* at 70.
[12] *See id.*
[13] *Id.* at 70-71.

9. **Assertion: TVT-O Issue Reports and MedWatch reports indicate substantial compliance with regulatory requirements**:[14] The analysis as to Paragraph (8) applies here as well. Delving into this area at all would require substantial discussion of the FDA's processes and what Ethicon did or did not do to comply with FDA guidelines.

10. **Assertion: Ethicon met pre-market requirements with the TVT-O**:[15] The first subheading in Mr. Ulatowski's analysis states that Ethicon's "510(k) submission meets FDA requirements."[16] There could not be a clearer indication that this opinion is foreclosed by the Court's prior orders.

11. **Assertion: The TVT-O labeling is substantially compliant with regulatory requirements and meets industry standards**:[17] Again, Mr. Ulatowski offers two opinions in one on labeling. The opinion that the labeling met FDA requirements creates many of the problems already discussed, including the necessity of a trial within a trial about what the FDA requires in labeling, and the suggestion that if the FDA is requiring certain labeling, then the FDA must have approved the device. The opinion that the labeling met industry standards is presumably derived from the FDA's guidelines—Mr. Ulatowski offers no other source for these "industry standards"—and thus that opinion presents the same problems. In addition, these warnings opinions should be excluded for reasons discussed in Section III. Mr. Ulatowski is not a warnings expert, and whether the warnings met "industry standards" is not relevant.

12. **Assertion: Ethicon's risk management policies substantially complied with regulations and industry standards**:[18] Mr. Ulatowski explains that the FDA requires compliance with ISO 14971, regarding risk management. Then he explains why, in his view,

[14] *Id.* at 74.
[15] *Id.* at 76.
[16] *Id.*
[17] *Id.* at 80.
[18] *Id.* at 82.

Ethicon has complied with this particular regulation.[19] Again, allowing such testimony would necessitate a barrage of evidence about what the regulation requires in particular circumstances, and the jury might be confused into thinking that the case turns on whether Ethicon did or did not comply—not on the actual state law at issue. And the discussion of FDA oversight would suggest that the device was FDA approved, forcing evidence on the 510(k) process as well.

13. **Assertion: The 510(k) review includes an analysis of the safety and effectiveness of the device**:[20] This Court has taken a contrary position in the past, and Fourth Circuit has said that this Court is correct. *In re C.R. Bard*, 810 F.3d at 920 (stating that the 510(k) process "does operate to exempt devices from rigorous safety review procedures"). The Court should exclude this opinion, which it has expressly rejected many times.

14. **Assertion: The press and litigants caused a surge of TVT MDR reports after 2011**:[21] This opinion starts by explaining the importance of the FDA communicating risks to physicians and patients.[22] Then, Mr. Ulatowski opines that increased media coverage and litigation, due in part to FDA statements, led to an increase in MDRs.[23] Addressing these opinions would require an analysis of the FDA statement, the effect of the statement on public information, the effect of public information in MDRs, and testimony about the MDRs themselves—what are they, what is their purpose, etc. Such testimony would take the trial way off track into the world of how the FDA operates.

15. **Assertion: The safety of laser cut mesh was properly verified according to regulations, and consistent with industry standards; and mechanically cut mesh was**

[19] *Id.* at 82-84.
[20] *Id.* at 84.
[21] Ulatowski TVT-O Report, Ex. D, at 87.
[22] *Id.*
[23] *Id.* at 88-89.

reasonably safe and effective:[24] Mr. Ulatowski's last opinion is another two-for-one, at least. The opinion as to the addition of laser-cut mesh ("LCM") goes directly to regulations. Regardless, the entire opinion addresses whether Ethicon followed proper procedures in changing some of the mesh from mechanically cut mesh ("MCM") to LCM. The purpose of the opinion seems to be that Ethicon followed FDA regulations that require proper validation for design changes. Thus, the opinion implicates a discussion of the FDA's processes and guidelines, leading to another side-show about regulations, their purposes, and Ethicon's success or failure in following them. Again, the legal issues in these cases will not turn on Ethicon's ability to follow FDA guidelines; they will turn on whether Ethicon's devices were properly designed, whether they contained adequate warnings, whether Ethicon breached any express or implied warranties, and other issues that will be defined by state law, not by the FDA.

This analysis shows that all of Mr. Ulatowski's opinions come from the perspective of someone who spent 16 years with the FDA.[25] All his opinions—on the TVT-O and other products—are directly or indirectly influenced by the question of whether Ethicon complied with FDA regulations. As this Court has recognized, the question of whether Ethicon complied with FDA regulations is not the issue to be presented to the jury. *See, e.g.*, *Bellew*, 2014 WL 6680356, at *10. Thus, Mr. Ulatowski's FDA-focused opinions should be excluded under Rule 702, in that they do not fit the case; and under Rule 403, in that their extremely limited probative value is substantially outweighed by the risks of unfair prejudice, confusing the issues, undue delay, and wasting time.

[24] *Id.* at 90.
[25] *See* Ulatowski CV at 2-3.

III. Mr. Ulatowski does not have the expertise to opine about the sufficiency of manufacturing processes or the content of warnings or patient brochures; and, any opinions that do not address those topics are irrelevant.

While all of Mr. Ulatowski's opinions should be excluded as being inextricably intertwined with issues regarding FDA compliance, this section will address additional reasons why his opinions on patient brochures, manufacturing, and product labeling should be excluded.

A. Patient brochures

Again using the TVT-O Report as an example, Mr. Ulatowski opines that the patient brochures do not constitute "labeling" under FDA rules, and that they are "consistent with industry standards and practices."[26] He has similar opinions in his other reports.[27] The opinions do not go to any issues that would be relevant regarding patient brochures—such as whether they adequately warn patients of risks, or whether they contain any misrepresentations regarding the product.

One reason that Mr. Ulatowski has no relevant opinions regarding patient brochures is that he has no expertise in patient brochures, as evidenced by his most recent deposition:[28]

> Q. And you have no opinion as to what adverse reactions should be in the patient brochure?
>
> A. That's correct. I think that requires medical opinions to assess that.[29]

That statement demonstrates that Mr. Ulatowski does not have the expertise to opine as to what information should be included in a patient brochure. Without that expertise he is

[26] Ulatowski TVT-O Report, Ex. D, at 67.
[27] *See* Ulatowski TVT Report, Ex. C, at 57; Ulatowski TVT Exact Report, Ex. E, at 76; Ulatowski Prolift Report, Ex. G, at 70.
[28] Mr. Ulatowski's last deposition in the MDL took place on Dec. 13, 2013, in relation to the *Lewis* case. As discussed above, this Court has consistently disallowed FDA evidence and has specifically excluded Mr. Ulatowski on that basis, so Plaintiffs have not felt it necessary to depose him.
[29] Ulatowski Deposition, Dec. 17, 2013, portions attached as Exhibit H, at 149:2-5.

incapable of giving a meaningful opinion about whether Ethicon's patient brochures were false or misleading, or about whether Ethicon's patient brochures adequately warned of risks.

B. Manufacturing defects

Remarkably, Mr. Ulatowski also opines in the area of manufacturing, despite a complete lack of any indication in his CV that he has any expertise in that area.[30] His opinion as to the TVT-O's manufacturing is limited to a review of certain FDA and Ethicon documents.[31] His opinions as to manufacturing with regard to the other TVT devices on which he opines are similarly limited.[32] Apparently, Mr. Ulatowski concludes that if there is no information suggesting a manufacturing defect in that limited set of documents, then there is "no evidence" of inadequate manufacturing.

Mr. Ulatowski is not qualified to discuss manufacturing, and he clearly has not engaged in a reliable methodology in opining that there is no evidence of a manufacturing defect. His report and CV do not indicate that he has so much as watched a product being manufactured—much less done so himself. The majority of Plaintiffs' cases will not involve a manufacturing defect. Generally, Plaintiffs contend that the flaws are in the design, and thus it is impossible to roll a safe version of the any of these products off of the assembly line. But if there is an allegation of a manufacturing defect for a particular product, then that allegation will require analysis of the policies and practices relevant to the manufacture of that specific device. This extremely general and unsupported opinion has no probative value and should be excluded.

[30] *See generally* Ulatowski CV, Ex. B.
[31] Ulatowski TVT-O Report, Ex. D, at 70.
[32] Ulatowski TVT Report, Ex. C, at 59; Ulatowski TVT Exact Report, Ex. E, at 58.

C. Product warnings in the IFU

Finally, Mr. Ulatowski should not be permitted to opine about the adequacy of the warnings in the IFU. As with patient brochures, Mr. Ulatowski admits that he does not have the expertise to opine in this area.

> Q. You don't have any opinions in this case as to whether the TVT IFU adequately discloses adverse reactions; correct?
>
> A. Well, I have an opinion about the adequacy of the labeling in regard to regulatory requirements, and I deferred on specifics regarding adverse effects to medical opinion, which is required, I think, in regard to assessing adverse events.
>
> Q. So you would agree with me that you have no opinion as to whether TVT IFU adequately discloses adverse reactions?
>
> A. Not beyond the fact that it meets the regulatory requirements for labeling, but as far as the ingredients of the adverse effects section, that I would defer to medical opinion.[33]

By "deferring to medical opinion," Dr. Ulatowski acknowledges that he does not have the necessary expertise to opine about the key issue in a warnings case. State law claims do not hinge on whether the warnings meet regulatory requirements; they hinge on whether the manufacturer adequately warned physicians and patients about the risks that were known or should have been known. *See, e.g.*, *Mohr v. Targeted Genetics, Inc.*, 690 F. Supp. 2d 711, 717 (C.D. Ill. 2010) (stating that to establish a failure-to-warn claim, plaintiff must prove that manufacturer knew or should have known about a risk that it failed to disclose); *Johnson v. Am. Standard, Inc.*, 43 Cal. 4th 56, 65, 179 P.3d 905, 910 (2008) (stating that the law imposes a duty on manufacturer "to warn of known or reasonably scientifically knowable risks"); *State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 913 (W Va. 2007) (stating that "because it is the prescription drug manufacturers who benefit financially from the sales of prescription drugs

[33] Ulatowski Dep., Ex. H, at 144:6-20.

and possess the knowledge regarding potential harms, and the ultimate consumers who bear the significant health risks of using those drugs, it is not unreasonable that prescription drug manufacturers should provide appropriate warnings to the ultimate users of their products").

Dr. Ulatowski's opinions do not provide any information that would help the jury to determine those issues. Instead, he opines that the TVT-O labeling is compliant with FDA requirements, and with industry standards.[34] He has similar opinions in relation to the other products at issue.[35] Such opinions only serve to distract the jury from the real issues in the case. By his own admission, Mr. Ulatowski has expertise to determine the real issue on a warnings claim—whether the warnings on a given product were adequate to warn physicians and patients about the risks associated with the products at issue.

The opinions and testimony on warnings encapsulates why the Court should exclude Mr. Ulatowski entirely. Mr. Ulatowski may be qualified to testify about FDA procedures and to offer opinions about MDRs and the 510(k) clearance process. But discussion of those issues will be excluded if this Court follows its prior orders regarding the FDA. Mr. Ulatowski has no expertise that goes outside of that realm. He cannot opine as to whether warnings, or brochures or manufacturing processes were actually safe. He can only opine as to whether they complied with what the FDA has determined is proper **procedurally**. Thus, Mr. Ulatowski has no relevant and reliable opinions to offer for the Ethicon Wave 1 cases.

CONCLUSION

This Court has previously held that FDA matters should be excluded from all trials in the MDL. If the Court does not reverse course on that issue, then all of Mr. Ulatowski's opinions that go to regulatory issues should be excluded under Rule 702, in that they do not fit the case;

[34] Ulatowski TVT-O Report, Ex. D, at 80.
[35] Ulatowski TVT Report, Ex. C, at 70; Ulatowski TVT Exact Report, Ex. E, at 61; Ulatowski Gynemesh PS Report, Ex. F, at 54; Ulatowski Prolift Report, Ex. G, at 64.

under Rule 402, because they are irrelevant; and under Rule 403, because the probative value of those opinions is extremely low, and the risks of unfair prejudice, confusing the issues, undue delay, and wasting time are all extremely high.

In addition, he does not have the expertise to opine as to manufacturing processes, the content of patient brochures, or the content of product warnings. As a result, the opinions that he does offer are irrelevant to the legal issues presented by product liability claims arising under state law.

For all of these reasons, Plaintiffs respectfully request that Mr. Ulatowski be excluded completely from testifying in any of the Ethicon Wave 1 cases.

Dated: April 21, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on April 21, 2016, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

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